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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/844,336	04/18/1997	PAMELA R. CONTAG	8678-004-999	7227

7590 06/27/2005

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EXAMINER
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ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

08/844,336

Applicant(s)

CONTAG ET AL.

Examiner

Robert A. Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 21-27 is/are rejected.
- 7) ☒ Claim(s) 24-26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 8-16-2004 has been entered.

The amendment and response filed on 1-24-2005 is acknowledged. Claim 1 has been amended. Claims 10-20 have been canceled. Claims 1-9 and 21-27 are pending and currently under examination.

### ***Claim Rejections Withdrawn***

The rejection of claims 1-9, 22-23 and 27 under 35 U.S.C. 102(b) as being anticipated by Karube et al. in light of Sleight et al. is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

### ***New Grounds of Rejection***

#### ***35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-9, 22-23 and 27 rejected under 35 U.S.C. 103(a) as being unpatentable over Contag et al. (U.S. Patent 5,650,135 – IDS filed on 10-5-98) in view of Georgiou et al. (U.S. Patent 5,348,867 – IDS filed on 1-22-99).

The instant claims are drawn to a biodetector comprising a signal-converting element (transmembrane fusion protein) coupled to a reporter gene (luciferase) via a responsive element (transcription activation element) and a transducer. Said biodetector may further comprise a bacterial cell.

Contag et al. disclose biocompatible compounds comprising an entity such as a bacterial cell and a light-generating moiety such as luciferase (see column 2, line 60 to column 3, line 3). Contag et al. further disclose said moiety could be expressed via *in situ* synthesis in the entity (i.e. expression of a heterologous bioluminescent protein in a transformed cell or the *in situ* activatable promoter controlled expression of a bioluminescent protein [see column 3, lines 11-14, column 4, lines 18-21 and column 7, lines 31-39]). Contag et al. also disclose luciferase

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vector constructs that can be adapted for use in transforming a variety of host cells including bacteria (see column 10, lines 60-63). Finally, Contag et al. disclose the use of antibodies and antibody fragments to confer specificity to the compound. Contag et al. differs from the claimed invention in that they do not explicitly disclose the recombinant expression of the antibodies or antibody fragments on the bacterial surfaces. Georgiou et al. disclose methods for the recombinant expression of heterologous proteins on the surface of bacteria (see abstract) including the expression of scFv (see column 6, lines 25-26). Since Contag et al. disclose the use of antibodies and antibody fragments as targeting moieties (see column 3, lines 38-40), it would have been obvious to one of skill in the art to use the heterologous scFv disclosed by Georgiou et al. in order to take advantage of the increase in specificity, diversity and ease of production associated with the resulting bioreceptor.

### ***Conclusion***

No claim is allowed.

Claims 24-26 are objected to as being dependent on rejected claims

Claims 24-26 are free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Robert A. Zeman". The signature is stylized with a large, sweeping "Z" and "M".

Robert A. Zeman

June 23, 2005